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Section 6
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a)

6.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned subsidiary of C.R. Bard, Inc.]
Address:	605 North 5600 West Salt Lake City, Utah 84116
Telephone Number:	(801) 595-0700 ext. 5428
Fax Number:	(801) 595-5425
Contact Person:	Henry Boland
Date of Preparation:	11 August 2008
Registration Numbers:	
Bard Access Systems:	3006260740
C. R. Bard:	2212754

6.2 Subject Device Information

DevicelTrade Name:	PowerLoc* Clear Safety Infusion Set
Common/Usual Name:	Huber Needle Intravascular Administration Set
Classification Name:	Intravascular Administration Set 21 CFR 880.5440 - Class II FPA - Intravascular Administration Set
Classification Panel:	General Hospital

6.3 Primary Predicate Device Information

Device/Trade Name:	PowerLoc* Safety Infusion Set
Common/Usual Name:	Huber Needle Intravascular Administration Set
Classification Name:	Intravascular Administration Set 21 CFR 880.5440 - Class II FPA - Intravascular Administration Set
Classification Panel:	General Hospital
510(k) Clearance:	K060812, concurrence date 14 July 2006

6.4 Secondary Predicate Device Information

Device/Trade Name:	Huber Clear* Safety Infusion Set
Common/Usual Name:	Huber Needle Intravascular Administration Set
Classification Name:	Intravascular Administration Set 21 CFR 880.5440 - Class II FPA - Intravascular Administration Set
Classification Panel:	General Hospital
510(k) Clearance:	K051009, concurrence date 12 July 2005

6.5 Device Description

The PowerLoc* Clear Safety Infusion Set is comprised of a standard non-coring Huber type needle and administration set with an integral needle-stick safety mechanism.

The PowerLoc* Clear Safety Infusion Set is a standard intravascular administration set with a non-coring Huber right angle needle and a manually activated needle-stick safety mechanism which reduces the risk of accidental needle-stick injuries by shielding the needle after use. The device is used to access surgically implanted vascular ports and indicated for use in the administration of fluids and drugs, as well as blood sampling.

The PowerLoc* Clear Safety Infusion Set is also indicated for power injection of contrast media into the central venous system through the Bard PowerPort* device family. The maximum recommended infusion rate is 5 *mils* for 19 gauge and 20 gauge, and 2 *mils* for 22 gauge needles.

The device functions in a similar manner to the predicate devices. The insertion site is prepared and the device is primed using a syringe containing normal saline and inserted into the port septum. Patency is confirmed and the device is dressed per institutional protocol. Removal of the device is accomplished by flushing per institutional protocol, stabilizing the implanted port with non-dominant hand and removing the device while simultaneously activating the needle-stick safety mechanism with the dominant hand.

6.6 Intended Use

The PowerLoc* Clear Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports

The intended use of the PowerLoc* Clear Safety Infusion Set has not changed when compared to the PowerLoc* and Huber Clear * Safety Infusion Sets.

6.7 Indications for Use

The indications for use of the PowerLoc* Clear Safety Infusion Set has not changed when compared to the predicate PowerLoc* Safety Infusion Set device.

The PowerLoc* Clear Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle-stick safety mechanism. The device is used to access surgically implanted vascular ports.

The PowerLoc* Clear Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with the PowerPort* device family, the PowerLoc* Clear Safety Infusion Set is also indicated for power injection of contrast media into the central venous system. For power injection of contrast media, the maximum

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recommended infusion rate is 5 mils for 19 Ga. and 20 Ga. needles and 2 mils for 22 Ga. needles.

6.8 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device? Yes. The subject device is compared to legally marketed predicate devices.

Does the new device have the same indication? Yes. The subject device and predicate PowerLoc* Safety Infusion Set device indication statements are identical.

Does the new device have the same technological characteristic, e.g. design, materials, etc.? No, not in all regards. The fundamental scientific technology of the device is the same as the predicate devices. None of the noted design differences have a major effect on the safety and effectiveness of the subject device or preclude its substantial equivalence to any significant degree.

Could the new characteristics affect safety or effectiveness? Yes. The design changes could affect safety or effectiveness.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes. The following FDA recognized standards were used to evaluate the device performance:

Guidance for Industry and FDA Review Staff- Intravascular Administration Sets Premarket Notification Submissions [510(k)], dated April 15, 2005

Guidance for Industry and FDA Staff- Medical Devices with Sharps Injury Prevention Features, dated August 9, 2005

ISO 11135:2007 - Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization

ISO 10993-1:2003 - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

ISO 10993-7:1995 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

ISO 11607-1:2006 - Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes

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ISO 14971:2007 - Medical Devices - Application of *Risk Management to Medical Devices*

These and other standards were used to determine the appropriate methods for evaluating the subject device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above referenced guidance document recommendations and additional standards, with favorable performance examination results available as objective evidence in each test category.

Performance data demonstrate equivalence? Yes. Performance data gathered in design verification met predetermined acceptance criteria and thus demonstrated that the subject **PowerLoc* Clear** device is substantially equivalent to the predicate **PowerLoc*** and **Huber Clear*** devices. The risks associated with use of the new device were found acceptable when evaluated through the risk management process including FMEA.

Conclusion
The subject **PowerLoc* Clear** Safety Infusion Set met all predetermined acceptance criteria of design verification evaluations through testing examination. Based on the FDA's decision tree, it is logically concluded through evidence that the subject device is substantially equivalent to the predicate devices, **PowerLoc*** Safety Infusion Set (K060812) and **Huber Clear*** Safety Infusion Set (K051 009).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2008

C.R. Bard, Incorporated
Mr. Henry Boland
Associate Regulatory Affairs Specialist
Bard Access Systems
605 North 5600 West
Salt Lake City, Utah 84116

Re: K082306
Trade/Device Name: PowerLoc* Clear Safety Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 11, 2008
Received: August 13, 2008

Dear Mr. Boland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5
Statement of Indications for Use

AUG 2 8 2008

510(k) Number (if known): _____

Device Name: **PowerLoc* Clear** Safety Infusion Set

Indications for Use:

The **PowerLoc* Clear** Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle-stick safety mechanism. The device is used to access surgically implanted vascular ports.

The **PowerLoc* Clear** Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with the **PowerPort*** device, the **PowerLoc* Clear** Safety Infusion Set is also indicated for power injection of contrast media into the central venous system. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s for 19 Ga. and 20 Ga. needles and 2 ml/s for 22 Ga. needles.

*PowerPort and PowerLoc are trademarks and/or registered trademarks of C.R. Bard, Inc. or an affiliate.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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